## **REMARKS**

This is intended to be a complete response to the Official Action mailed March 23, 2007, in which claims 1, 19, 22, 24, 25, 27 and 28 were rejected. Applicants have canceled claims 1, 19, 22, 24, 25, 27 and 28 and provided new claims 29-36.

## Claim Rejections - U.S.C. § 112

In the Office Action dated March 23, 2007, the Examiner rejected claims 1, 19, 24, 25, 27 and 28 under § 112, first paragraph, as failing to comply with the written description requirement. Without agreeing to this assessment, the Applicants herein amend the application to cancel claims 1, 19, 24, 25, 27 and 28.

The Examiner argues that "the matters at issue here is not whether the underlying theories are sound, but how to translate the theories into clinical benefit, to a therapeutic process for treating sickle cell disease." However, on page 3 of the Office Action dated March 23, 2007, the Examiner states that "applicant has shown in cell culture that supplying a nucleic acid expressing ferritin-H suppresses expression of the beta-globin gene, and leading to renewed expression of gamma-globin." In an effort to expedite allowance, the Applicants have provided new claims 29-35 addressing methods for treating a beta-globin producing cell comprising: providing at

least one beta-globin producing cell; providing a vector encoding ferritin-H; and inserting the vector encoding ferritin-H into the at least one beta globin producing cell, whereby ferritin-H is produced in the cell and represses production of beta-globin proteins in the cell. Applicants believe that the claims are fully disclosed and enabled in the specification, and that these claims should be allowed.

## Claim Rejections - U.S.C. § 102

In the Office Action dated March 23, 2007, the Examiner rejected claim 22 as being anticipated by *Broxmeyer et al.* and claims 1, 19, 22 and 27 as being anticipated by *Adams et al* and *Sowemimo-Coker*.

Applicant cancels claim 22 and provides new claim 36 directed to a pharmaceutical composition comprising an <u>isolated</u> gene encoding ferritin-H and a suitable transfection vector, wherein the composition is provided in a pharmaceutical formulation for injection. Applicants previously argued that *Broxmeyer et al.* should not anticipate claim 22, in part, because it did not provide a pharmaceutical. The Examiner did not find this a persuasive argument because Applicants did not include this limitation in the body of their claim. This limitation is now in the claim body of claim 36.

Applicants also submit that the limitation of an "isolated gene" in new claim 36, avoids anticipation by a teaching of blood transfusion in *Adams et al* and *Sowemimo-Coker*. Additionally, new claims 29-35 are drawn to a

method for treating a beta-globin producing cell comprising: providing at least one beta-globin producing cell; providing a vector encoding ferritin-H; and inserting the vector encoding ferritin-H into the at least one beta globin producing cell, whereby ferritin-H is produced in the cell and represses production of beta-globin proteins in the cell. Accordingly, claims 29-35 are also not anticipated by the blood transfusion taught in *Adams et al* and *Sowemimo-Coker*.

## **CONCLUSION**

In view of the above, Applicants respectfully suggest the claims are now in a condition for allowance and request issuance of a Notice of Allowance thereof.

Respectfully submitted,

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